IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
DURHAM DIVISION

RIVER'S EDGE PHARMACEUTICALS, LLC, Plaintiff, v. GORBEC PHARMACEUTICAL SERVICES, INC., and J. MICHAEL GORMAN, Defendants.	)	No. 1:10-cv-991 – UA-PTS

PLAINTIFF'S BRIEF IN SUPPORT OF MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

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INTRODUCTION

Since 2007, River's Edge Pharmaceuticals, LLC, ("River's Edge") has paid Gorbec Pharmaceutical Services, Inc. ("Gorbec") REDACTED to serve as its agent to the FDA, to prepare formulations for its product ideas and to obtain regulatory approval for generic drugs and medical devices. If these products win the competitive race to gain FDA approval and get to market, they will be worth REDACTED . River's Edge has invested the lifeblood of its company into the products, and they represent its future. Now, with concepts tested, regulatory approval near, and River's Edge's future in its hands, Gorbec is breaching fiduciary duties, converting the intellectual property and regulatory approvals, and using its position of trust and control to demand millions from River's Edge.

Time is of the utmost essence. Commercial success in generic pharmaceuticals is dependent on being first to obtain FDA approval and first to market. The products at issue are in critical stages of the approval process, where any misstep may cost the race, end the opportunity, and waste the REDACTED invested. Simply put, Gorbec – which, as River's Edge's agent to the FDA, knows better than anyone else – will cause irreparable harm to River's Edge unless immediately enjoined.

Accordingly, River's Edge seeks an injunction that, among other things: (1) requires Gorbec to release the intellectual property and regulatory applications it was hired to prepare and present to the FDA (the "Work Product"); (2) prohibits Gorbec from utilizing or disclosing the Work Product; (3) prohibits Gorbec from competing against its

principal; (4) requires Gorbec to cooperate in transferring the technology to another agent; and (5) requires Gorbec to assist in maintaining the relationship with the FDA during the transfer.

This relief is justified by the critical time constraints and the overwhelming evidence against Defendants, including admissions showing intent and knowing malfeasance. This evidence demonstrates that River's Edge is likely to prevail on the merits, that it is suffering immediate and irreparable harm, that the balance of the conveniences weighs heavily in its favor, and that the relief requested is appropriately limited and in the public interest.

THE QUESTION PRESENTED

Has River's Edge demonstrated that it is likely to prevail on the merits, that it will suffer irreparable harm absent interim relief, that interim relief is favored by the balance of the conveniences, and that interim relief is in the public interest, such that River's Edge should have a TRO and preliminary injunction?

FACTS

A. The Regulatory Framework

Manufacture and sale of drugs and devices is regulated by the FDA. There are two ways a drug can be approved, depending on whether the drug is an innovator drug (the first of its kind) or a generic (a bioequivalent alternative to an innovator). 21 U.S.C., § 355(a). Innovator drugs obtain approval through submission of a New Drug Application ("NDA") to demonstrate that the drug is safe and effective. 21 USC §

355(d). NDAs require extensive testing, take years, and cost tens of millions of dollars. As a result, innovator drugs are typically expensive, heavily advertised "brand name" drugs. Ex. A (Murphy Decl.), ¶ 8.

Congress encourages the use of generics to reduce the overall cost of healthcare. Generic drugs obtain approval through an Abbreviated New Drug Application ("ANDA"), which determines whether the generic is bioequivalent to the innovator, safety and efficacy having already been established. 21 C.F.R. § 314.91 et seq.; 21 U.S.C. § 355(j). Although shorter, this process often still takes years and costs millions.

The key to success in generic pharmaceuticals is being first to obtain regulatory approval and first to market with the newly approved drug. Most states require pharmacists to offer patients the least costly alternative to a prescription product and pharmacies generally profit more by selling generics, creating great incentive to substitute generics for innovators. By contrast, there is little incentive to carry more than one generic, as normally only the least expensive is sold. As a result, the first to market typically takes and holds the market. Ex. A, ¶¶ 9-10.

This race to market is central to this action and request for emergency relief. The marketplace has many sophisticated players and is highly competitive. Any delay in development or approval is likely to cost the race, the opportunity, and even the underlying investment. Moreover, as the process is confidential, no drug developers know where they stand, and all must decide to initiate and pursue regulatory approval "in the dark." Ex. A, ¶ 11.

Many things can delay a party in this race, and Defendants are using them all for leverage. First, any substantive change in drug formulation requires new approval from the FDA and is likely to cause significant delay. 21 C.F.R. §§ 314.60(b), 314.96, 314.70(b), and 314.97. Drugs are approved with a master formula that dictates the ingredients and the manner by which the drug must be manufactured. This formula is the basis of FDA approval and must be followed precisely. 21 C.F.R. § 314.50(d)(1).

Second, regulatory approval is specific to the manufacturing facility identified in the application. 21 C.F.R. § 314.50(d)(1)(ii)(a). Changes in manufacturing facility require formal "technology transfer" to a new facility and create significant delay. 21 C.F.R. §§ 314.60(b), 314.70(b).

Third, failure to respond fully and timely to communications from the FDA will delay an application or cause it to fail. ANDAs involve a dialogue with the FDA, usually requiring ongoing adjustment to the application. The FDA sets conferences, 21 C.F.R. § 314.102, and issues deficiency notices, which must be timely addressed to avoid delay. 21 C.F.R. § 314.102. Many pharmaceutical companies lack the manufacturing capability or regulatory expertise to prosecute applications through the FDA. Accordingly, the process contemplates use of agents such as Gorbec. 21 C.F.R. § 314.50(a)(5) ("The applicant . . . or . . . agent . . . shall sign the application."); 21 C.F.R. § 314.94(a)(1). However, the application and approvals belong to the principal. 21 C.F.R. § 314.72 (providing for applicants' transfer of ownership).

Several other aspects of the regulatory framework are relevant. First, while the majority of products at issue are pharmaceutical products, there is a similar process for approval of medical devices called a 510(k) submission. Second, while the majority of drugs require an NDA or ANDA, two types do not. The FDA permits the sale of certain drugs that are "generally recognized as safe and effective" ("GRASE Drugs"). It also allows sale of certain, as of yet ***un***approved drugs that have been recognized as safe, but not yet established as effective ("DESI Drugs"). Ex. A, ¶¶ 18-19.

B. <u>The Parties and Their Relationship</u>

River's Edge was established in 2003 by Brendan Murphy, with the mission of providing reasonably priced alternatives to costly "name brand" pharmaceuticals. Initially, it focused on DESI Drugs because they required less up-front capital. However, River's Edge's business has evolved to generics with ANDAs. Ex. A, ¶ 20.

Before the events that give rise to this litigation, the parties had a relationship of trust and confidence. The relationship between a pharmaceutical company and a contract manufacturer is one of great trust and confidence because the manufacturer has access to the company's most confidential information, disclosure of which would destroy competitive advantage. A defect in any of the drugs could cause injury to the public and create liability to the company. The manufacturer is also critical to the company's relationship with the FDA, as the company is held responsible for the manufacturer's compliance with FDA standards. Ex. A, ¶¶ 21-23.

The relationship of trust and confidence between River's Edge and Defendants developed from this dynamic. When River's Edge started in 2003, Defendant Gorman ran a contract manufacturer called Harmony Laboratories ("Harmony"); Harmony became one of River's Edge's primary manufacturers. Indeed, the relationship was so strong, Brendan Murphy hired Defendant Gorman's brother to run an affiliated company. Ex. A, ¶¶ 25-26.

This relationship deepened in 2007, after Harmony was sold. After consultation with Murphy, Gorman decided to form Gorbec to specialize in representing pharmaceutical companies before the FDA. A separate company owned by Murphy's wife made a substantial minority investment in Gorbec. Ex. A, ¶¶ 27-28.

By 2007, River's Edge had obtained the financial strength to work on ANDA and 510(k) product ideas. It was logical to engage Gorbec to shepherd these product ideas through the FDA as River's Edge's agent. Indeed, this was and is Gorbec's primary business. Ex. A, ¶¶ 29-30. Gorbec's web site states:

> Gorbec Pharmaceutical Services Inc. was founded on January 1, 2007 by sole proprietor and businessman Mike Gorman, with a purpose of offering a broad range of services in support of the drug development process. **Our goal is to transform *your concept* into a product that meets FDA requirements** and your performance criteria, while working within a timeline and a budget.
>
> Our focus is on the segment of small volume niche drugs that treat narrowly defined conditions and disease states, recognizing that most large facilities cannot cost effectively handle these types of products. **We can guide *your product* through the developmental stages**, **offering analytical support, scale-up, pilot plant manufacturing, and electronic FDA submission.**

Gorbec's services include:

> . . . complete formulation development services for topical and oral products including liquid, semisolid and solid dosage forms **with an emphasis on guiding your product through the ANDA, 510(k), 505(b)(1) and 505(b)(2) NDA submission process.**
> . . . .
> Let us take your product to market.

Ex. B (emphasis added).

River's Edge orally engaged Gorbec as its agent and developer in 2007, with an understanding that Gorbec would bill on an ongoing basis for services rendered. Since then, River's Edge has paid Gorbec REDACTED in a series of purchase orders to serve as its agent, develop product formulations and obtain regulatory approvals. Gorbec has also directed River's Edge to testing facilities that River's Edge paid to perform testing required by the FDA, has taken sole possession of the test results, and has filed ANDAs and 510(k)s for River's Edge using the formulations it developed for River's Edge, identifying its own manufacturing facility as the place where the drugs will be made – all as the agent of River's Edge. Gorbec has also been paid REDACTED to manufacture River's Edge's DESI Drugs. Ex. A, ¶ 33.

River's Edge has placed its ANDA and 510(k) business and its future entirely in Gorbec's hands. To-date, Gorbec has worked on all of River's Edge's ANDA proprietary drug ideas and all its 510(k) proprietary devices, and has submitted REDAC ANDA and REDACTED 510(k) applications on behalf of River's Edge. It has also become River's

Edge's express agent with, and sole contact to, the FDA. Ex. A, ¶ 34. Each ANDA submitted by Gorbec expressly identifies it as River's Edge agent:

> **APPLICANT INFORMATION**
> NAME OF APPLICANT
> River's Edge Pharmaceuticals LLC
>
> **AUTHORIZED U.S. AGENT NAME & ADDRESS** (*Number, Street, City, State, Zip Code, telephone & FAX number*) IF APPLICABLE
>
> Gorbec Pharmaceutical Services, Inc.

Ex. A, ¶ 35(emphasis in original); Ex. C, Example of Gorbec ANDA Cover Sheet. Gorbec also routinely reminded the FDA that Gorbec was the contact for inquiries concerning River's Edge applications, saying:

> Enclosed is an Abbreviated New Drug Application electronic submission from Gorbec Pharmaceutical Services Inc. acting as a sponsor for River's Edge Pharmaceuticals LLC.
> . . .
> The contact person for this submission is:
>
> Matthew R. Popp
> Gorbec Pharmaceutical Services, Inc.

Ex. A, ¶ 36; Ex. D, Example of Gorbec Cover Letter. Gorbec had River's Edge confirm this relationship with the FDA. Ex. A, ¶ 37; Ex. E, Example of Confirmation Letter.

Until recently, all parties agreed that River's Edge owned all the Work Product. For example, a Pharmaceutical Quality Agreement[1] executed March 2, 2010 (Ex. F), recites that, "Company [River's Edge] owns the regulatory applications for the Products." Ex. A, ¶ 38; Ex. F at 9, ¶ 6.1.

[1]The Quality Agreement was executed in anticipation of Gorbec manufacturing the products when regulatory approval is secured.

As recently as October 12, 2010, Gorman sent an e-mail (Ex. G) to Murphy stating that, "We have built great value for you, [product name] alone you said you would turn down five million. **I am happy for you; you took the risk and should get the reward**." Ex. A, ¶ 39; Ex. G (emphasis added).

Gorbec's price quotations to River's Edge (Ex. H) provide:

> **Section 9. Hold Harmless**
> River's Edge Pharmaceuticals is a company that develops and has produced by third parties various generic drug formulations. As a result of their experience River's Edge is fully aware of the risk associated with the development, filing and production of generic drugs. The success and ultimate approval by the FDA is a risk that River's Edge is fully prepared to take.

Ex. A, ¶ 40; Ex. H at 3, § 9.

Unfortunately, opportunity, albeit improper, has changed Gorbec's position.

C. Gorbec Becomes A Disloyal Agent, Taking What It Was Hired To Deliver

Despite the necessary relationship of trust and confidence and the history the parties shared, Defendants are now actively exploiting River's Edge's dependence on them and critical time constraints for their benefit. In August of 2010, Gorbec proposed a manufacturing agreement (Ex. I) that would give it complete ownership of the Work Product (including formulas, technological knowhow, manufacturing methods, and procedures and all records). Ex. A, ¶¶ 46-47; Ex. I at 15, § 10.2(b). Without the Work Product, the ANDAs are worth nothing to River's Edge, as they cannot be used or transferred to another manufacturer without the Work Product. Ex. A, ¶ 48.

Although River's Edge refused to sign the agreement and rejected the proposal, Gorbec has asserted ownership and dominion over the Work Product and kept it from River's Edge. A recent e-mail from Gorman (Ex. J) claims that "Gorbec intellectual property has always been and will continue to be owned by Gorbec. A copy of each filling is sent to rivers edge with gorbecs intellectual property removed in every case. This policy which has been in place from the first filling has not been questioned nor been deviated from." *[sic]* Ex. A, ¶ 49; Ex. J.

The same e-mail also shows Gorbec abandoning its agency role and withholding critical information from River's Edge:

> **While we are under no obligation to provide Cassie [River's Edge's project manager] with any deficiency notices nor to respond to these** we have to the best of my knowledge sent them to her along with our charge for the work which remains unpaid as of this writing.[2]

Id. (emphasis added).

The scope of the betrayal was clarified in recent correspondence from Gorbec's counsel (Ex. K).[3] Knowing it could destroy all commercial value in the ANDAs and 510(k)s, Gorbec gave River's Edge three unacceptable alternatives: (1) Pay $20 million dollars for the Work Product it already purchased (*Id.*, p. 3); (2) Assign the Work Product to Gorbec for a refund of the money paid, giving Gorbec the "reward" for the "risk" River's Edge took (*id.*); or (3) Pay Gorbec $215,850 for copies of the Work Product, while Gorbec competes with the Work Product and the facilities already specified,

[2] River's Edge's records prove it has actually *over*paid.
[3] Consistent with Rule 408 of the Federal Rules of Evidence, this letter is being submitted to demonstrate the need for emergency relief as opposed to liability or damages.

assuring Gorbec will win the race to while River's Edge pursues a technology transfer. Ex. A, ¶¶ 50-51; Ex. K.

Twelve days later, Gorbec increased the pressure, threatening in an e-mail, a copy of which is attached as Ex. L, to begin competition immediately if River's Edge did not accede to its demands. Ex. A, ¶¶ 50-51; Ex. L.

D. Irreparable Harm

Put simply, River's Edge took all the risk, and invested its business and financial resources to be first to gain regulatory approval and get to market for dozens of generic products and medical devices. Gorbec took no risk, ensconced itself as River's Edge's agent, required payment in advance for services, and got paid REDACTED. Now that River's Edge's opportunities are coming to fruition, Gorbec is exploiting its trusted position to destroy the opportunities with delay and tortious conduct to extort River's Edge. Specific actions include actual or threatened: (1) abandonment of its role as agent to the FDA; (2) refusal to provide River's Edge complete documentation of ANDA and 510(k) filings; (3) conversion of the research results necessary for regulatory approval; (4) suspension of ongoing stability testing of all products[4]; (5) refusal to provide master drug formulations and drug master files, and conversion of them; (6) threats to use the information withheld from River's Edge in competition with River's Edge; and (7) refusal to provide critical information and communications with the FDA necessary to obtain approval and respond to Notices of Deficiency.

[4] The FDA requires that all drugs undergo stability testing to determine shelf life. If stability testing is suspended, it must be restarted from scratch and will delay any approval.

Putting aside that Gorbec's disloyalty will require a technology transfer to a loyal manufacturer that will inevitably delay and compromise FDA approval, the actions above will be fatal to River's Edge's effort to be first to market, and will allow Gorbec, whose facility is listed in the ANDAs, who is familiar with the formulations, and who has been communicating dealing with the FDA as River's Edge's agent, to beat River's Edge, its principal, in the race to the market. Ex. A, ¶¶ 52-59.

ARGUMENT

"The traditional office of a preliminary injunction is to protect the status quo and to prevent irreparable harm during the pendency of a lawsuit ultimately to preserve the court's ability to render a meaningful judgment on the merits." *Sun Microsystems, Inc. v. Microsoft Corp. (In re Microsoft Corp. Antitrust Litigation*, 333 F.3d 517, 525 (4th Cir. 2003). "A preliminary injunction is always appropriate to grant intermediate relief of the same character as that which may be granted finally." *De Beers Consol. Mines, Ltd. v. United States*, 325 U.S. 212, (1945).

A party seeking a preliminary injunction must establish: (1) it is likely to succeed on the merits; (2) it is likely to suffer irreparable harm in the absence of preliminary relief; (3) the balance of equities tips in its favor; and (4) the injunction is in the public interest. *Winter v. Natural Res. Defense Council, Inc*., ___ U.S. ___, 129 S. Ct. 365, 374, (2008); *Real Truth About Obama, Inc. v. FEC*, 607 F.3d 355, 356 (4th Cir. 2010). All factors are present here.

A. River's Edge Is Likely To Succeed On the Merits

The United States Supreme Court addressed a similar, but less egregious fact scenario almost 90 years ago. Its holding applies equally today:

> Other meaning to the contract would confuse the relation of the parties to it – take from the Axle Company the inducement the company had to make it – take from the company the advantage of its exclusive use and subject the company to the rivalry of competitors. And yet, such, we think, is the contention of Peck. He seems somewhat absorbing in his assertion of rights. He yields to the Axle Company a shop right only, free from the payment of royalty but personal and temporary – not one that could be assigned or transferred. Peck, therefore, virtually asserts, though stimulated to services by the Hess Company and paid for them – doing nothing more than he was engaged to do and paid for doing – that the product of the services was so entirely his property that he might give as great a right to any member of the mechanical world as to the one who engaged him and paid him – a right to be used in competition with the one who engaged him and paid him. We cannot assent to this.

Standard Parts Co. v. Peck, 264 U.S. 52, 60 (1924).

1. Gorbec Is Breaching Its Fiduciary Duties

North Carolina recognizes two types of fiduciary relationships: those created by defined legal relationships (e.g., agent/principal or lawyer/client) and those which arise from other relationships "that exist as a fact, in which there is confidence reposed on one side, and the resulting superiority and influence on the other." *S.N.R. Mgmt. Corp. v. Danube Partners, 141, LLC*, 189 N.C. App. 601, 613, 659 S.E.2d 442, 451 (2008); *Patterson v. Strickland*, 133 N.C. App. 510, 516, 515 S.E.2d 915, 919 (1999). Such relationships are broadly defined. *Dalton v. Camp*, 353 N.C. 641, 651, 548 S.E.2d 704, 708-14 (2001). Indeed, fiduciary duty "extends to any possible case in which a fiduciary

relation exists in fact, and in which there is confidence reposed on one side, and resulting domination and influence on the other." *Abbitt v. Gregory*, 201 N.C. 577, 598, 160 S.E. 896, 907 (1931).

> The duty of a fiduciary is one of the strongest recognized by law.
>
> Where a confidential or fiduciary relationship exists, it is the duty of the person in whom the confidence is reposed to exercise the utmost good faith in the transaction and to refrain from abusing such confidence by obtaining any advantage to himself at the expense of the confiding party.

Vail v. Vail, 233 N.C. 109, 114, 63 S.E.2d 202, 206 (1951). So strong is the duty that the burden is on the fiduciary to establish the propriety of its conduct. *Willetts v. Willetts*, 254 N.C. 136, 141, 118 S.E.2d 548, 551 (1961) (holding that fiduciary relationship raises a presumption of fraud that "annuls the act unless such presumption be rebutted by proof that no fraud was committed, and no undue influence or moral duress exerted").[5]

Here, Gorbec owes a fiduciary duty to River's Edge as a result of its engagement as River's Edge's agent and its relationship of confidence and control. Gorbec was River's Edge's express agent for purposes of developing and obtaining ANDAs and 510(k)s. As described in its own marketing materials, Gorbec is in the business of taking product ideas, converting them to formulations that will be accepted by the FDA and representing pharmaceutical companies before the FDA. Accordingly, Gorbec filed ANDAs and 510(k)s expressly identifying itself as the "agent" of River's Edge, and had River's Edge send letters to the FDA confirming its authority.

[5] This means that River's Edge needs only to demonstrate that Gorbec is unlikely to be able to show that its actions have been appropriate. Clearly they have not.

The evidence also demonstrates Gorbec was in such a position of trust and control over River's Edge's ANDA and 510(k) business that it is a fiduciary to River's Edge. Gorbec was entrusted with River's Edge's proprietary product ideas, has exclusive control over the master formulations River's Edge hired it to produce, has exclusive control over the manufacturing facility tied to each ANDA, has exclusive lines of communications with the FDA and has controlled River's Edge's responses to the FDA for years. Simply put, as a result of its confidential position, Gorbec has complete control over River's Edge's ability to enter and profit from the generic market, and its future. This is the exact scenario that gives rise to a fiduciary duty in fact.

It is also clear that Gorbec has breached and threatens to continue breaching its fiduciary duties. Contrary to all law, equity and conscience, Gorbec: (1) is asserting ownership over the intellectual property of its principal; (2) is attempting to convert River's Edge business opportunities for itself; (3) has refused to provide River's Edge with information regarding the FDA or respond to notices from the FDA; (4) is attempting to take tens of millions of dollars from River's Edge; and (5) is using time constraints to increase its leverage. This is the definition of a breach of fiduciary duty, made worse by Gorman's admission that River's Edge was entitled to the rewards for the risk it alone took. Accordingly, on this count alone, River's Edge can demonstrate that it is likely to prevail on the merits.

2. Other Claims On Which River's Edge Is Likely to Prevail

River's Edge has focused this Brief on the claim for breach of fiduciary duty because it demonstrates the level of Defendants' malfeasance. However, as demonstrated by the Supreme Court's analysis in *Standard Parts v. Peck*, *supra*, a party hired to create work product for another cannot then unilaterally use that work product for its own advantage. Gorbec seeks to do just that, giving rise to equally compelling claims for fraud, breach of contract, conversion of the physical embodiments of the Work Product and regulatory applications,[6] among other claims. Even on the basis of the evidence already available, River's Edge is substantially likely to prevail on these as well.

B. River's Edge Is Suffering And Will Suffer Irreparable Harm

It is well settled that a party suffers irreparable harm when money damages cannot be easily ascertained or would be inadequate. *Multi-Channel TV Cable Co. v. Charlottesville Quality Cable Operating Co.,* 22 F.3d 546, 552 (4th Cir. 1994). Many injuries cannot be remedied by monetary awards. For instance, loss of a business is irreparable harm. *Federal Leasing, Inc. v. Underwriters at Lloyd's*, 650 F.2d 495, 500 (4th Cir. 1981). Loss of customers constitutes irreparable harm. *Merrill-Lynch, Pearce, Fenner and Smith v. Bradley*, 756 F.2d 1048, 1055 (4th Cir. 1985). Loss of goodwill, advertising opportunities, market share and harm to competitive position constitute irreparable injury. *R.J. Reynolds Tobacco Co. v. Phillip Morris Inc.*, 60 F. Supp.2d 502,

[6] *See Harris v. Matthews*, 361 N.C. 265, 283, 43 S.E.2d 566, 577 (2007) (quoting *In re Legg*, 325 N.C. 658, 669, 386 S.E.2d 174, 180 (1989)) ("Conversion is an unauthorized assumption and exercise of the right of ownership over goods or personal chattels belonging to another, to the alteration of their condition or the exclusion of an owner's rights.").

509 (M.D.N.C. 1999). As this Court recently recognized, even the "loss of proprietary information may constitute irreparable harm." *Philips Elecs. N. Am. Corp. v. Hope*, 631 F. Supp. 2d 705, 711 (M.D.N.C. 2009).

Here the tortious conduct of Defendants has put River's Edge at imminent risk of suffering irreparable harm under each of these tests and more. Any delay in the prosecution of its ANDAs and 510(k)s is likely to cause River's Edge to lose the race to be first to market. REDACTED

Absent an injunction, it will be extremely difficult for River's Edge to demonstrate when it would have had its products approved, whether it would have been first to market, how the market would have reacted, and the sales it would have made. This is the essence of damages that cannot be easily ascertained.

Moreover, as described in the Declaration of Brendan Murphy, Exhibit A, absent an injunction, Gorbec's actions will REDACTED

it will have lost proprietary information, its intellectual property and trade secrets, its customers and market share, and its hard-earned reputation. Ex. A, ¶. 60. This case presents all aspects of imminent irreparable harm.

C. <u>The Balancing Of Conveniences Heavily Favors River's Edge</u>

The balance of conveniences also weighs heavily in favor of River's Edge and against Defendants. By Michael Gorman's own admission, River's Edge took the risk

necessary to develop the ANDAs and 510(k)s by spending REDACTED to develop the technology and formulations and engaging Gorbec to prosecute the applications with the FDA. *See* Ex. G. River's Edge paid REDACTED to Gorbec and significant money to third party testing facilities that sent their results to Gorbec. River's Edge now stands on the brink of achieving a competitive edge that was developed by its foresight, tolerance for risk, and payment of capital. Again, by Gorman's own admission, it is River's Edge that has earned the rewards that come with such innovation and effort. All of this, REDACTED if Defendants are not immediately enjoined. The weight of this harm cannot be underestimated or quantified.

By contrast, there can be little or no harm to Gorbec if an injunction is granted. Putting aside the obvious – that Gorbec cannot claim legitimate harm from an injunction against illegal and tortious conduct – an injunction causes it little or no harm for several reasons. First, by its own admissions, it has already been paid virtually everything to develop the intellectual property, knowhow, ANDAs, and 510(k)s that are at issue. Even if the demands asserted by Gorbec in Ex. K (at p. 2) were valid (which they are not), the potential loss to Gorbec is not only readily identifiable and therefore remediable at law, but is also a mere drop in the bucket compared to the stakes for River's Edge.

Second, Gorbec can claim no legitimate interest or expectation in developing the products at issue, as the ideas, the cost and the commercial drive came from River's Edge. At most, an injunction would merely delay Gorbec's ability to enjoy an unearned,

unexpected, and undeserved windfall. Here again Gorman's own words show this to be true: **"you took the risk and should get the reward."** Ex. G (emphasis added).

D. Public Interest

Finally, there can be little question that the injunction requested is in the public interest. First, the public has a strong interest in knowing that fiduciary, trade secret, and contractual interests will be upheld and violations will be prevented. Second, the public has a strong interest in seeing the products at issue proceed toward approval and market, as the introduction of generic products is critical to controlling the cost of healthcare.

By contrast, there is nothing about the injunction that will cause injury to the public. River's Edge is a successful seller of pharmaceuticals with a proven track record of getting products to market. Allowing it to go forward as it bargained for and paid to do can injure no one.

CONCLUSION

Based on the foregoing, River's Edge requests hearing on its Motion for TRO and preliminary injunction and issuance of the proposed Order River's Edge has submitted in connection with its Motion for Temporary Restraining Order and Preliminary Injunction.

Respectfully submitted this 25th day of January, 2011.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing document was this day served by electronic means in accordance with Local Civil Rule 5.4.

I further certify that I have this day served a copy of the foregoing document by depositing a copy thereof in the United States Mail, postage prepaid, addressed to Defendants' counsel at the last address known to me:

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